K131120

STERIS®

JUL 16 2013

510(k) Summary
For
Amsco® V-PRO® 1, V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems

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Summary Date: April 19, 2013

1. Device Name

Trade Name:	Amsco® V-PRO® 1, V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems
Common/usual Name:	Vapor Phase Hydrogen Peroxide Sterilizer
Classification Name:	Sterilizer, Ethylene Oxide Gas 21 CFR 880.6860 Product Code MLR

2. Predicate Devices

Amsco® V-PRO® 1 Low Temperature Sterilization System (K062297, K102394, K111810 and K120632)
Amsco® V-PRO ®1 Plus Low Temperature Sterilization System (K083097, K102394, K111810 and K120632)
Amsco® V-PRO® maX Low Temperature Sterilization System (K102330, K112760 and K120632)

3. Description of Device

The Amsco V-PRO 1, V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems are vaporized hydrogen peroxide sterilizers. The V-PRO Sterilizers use VAPROX® HC Sterilant to sterilize the intended devices through exposure to vaporized hydrogen peroxide (VHP). The pre-programmed V-PRO cycles all utilize a conditioning phase, a sterilization phase and an aeration phase. The packaged sterilized devices are ready for use at the completion of the cycle; no cool down or aeration period is required.

The three V-PRO Sterilizers share common cycles as outlined in **Table 5-1**.

Table 5-1: V-PRO Cycles Provided in the V-PRO Family of Sterilizers

Cycle	V-PRO 1	V-PRO 1 Plus	V-PRO maX
Lumen Cycle	X	X	X
Non Lumen Cycle	*	X	X
Flexible Cycle			X

* Shaded cell indicates that the V-PRO Sterilizer does not include the identified cycle.

All three sterilizers contain the Lumen Cycle. The purpose of this submission is to update the indications for use statement cleared under K120632. No modifications were made to the Sterilizers' hardware or software for the proposed modification to the Lumen Cycle stainless steel lumen claims.

The accessories that have been validated for use in the three V-PRO Cycles and the Premarket Notification submission references under which the accessories were cleared for the cycles are listed in Table 5-2.

Table 5-2. Accessories Validated for Use in the V-PRO Sterilizers

Accessory	Submission Reference		
	V-PRO Lumen Cycle	V-PRO Non Lumen Cycle	V-PRO Flexible Cycle
Verify V24 SCBIs	K073244, K090514	K083097	K102330
Verify Vaporized VH2O2 Process Indicators	K091174	K091174	K102330
V-PRO Sterilization Trays	K070769, K103226	K083097, K103226	K102330, K103226
Vis-U-All Tyvek Pouches	K070765 K071087 K090371	K083097 K090371	K102330

4. Intended Use

The purpose of this submission is to update the indications for use statement cleared under K120632. No modifications are being made to the V-PRO Sterilizers' intended use with respect to the Non Lumen and Flexible Cycles.

The Amsco V-PRO 1, V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems, with VAPROX HC Sterilant, are vaporized hydrogen peroxide sterilizers intended for use in the terminal sterilization of cleaned, rinsed and dried reusable metal and nonmetal medical devices used in healthcare facilities. The pre-programmed sterilization cycles (Lumen Cycle, Non Lumen Cycle, and Flexible Cycle) operate at low pressure and low temperature and are thus suitable for processing medical devices sensitive to heat and moisture.

The Amsco V-PRO 1, V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems' **Lumen Cycle**, the subject of this submission, can sterilize:[a]

- Lumened and non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
- Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations:[a]
    - single channeled devices with a stainless lumen that is ≥ 0.77 mm internal diameter (ID) and ≤ 500 mm in length

- dual channeled devices with stainless steel lumens that are ≥ 0.77 mm ID and ≤ 527 mm in length
- triple channeled devices with stainless steel lumens that are either
  - ≥ 1.2 mm ID and ≤ 275 mm in length
  - ≥ 1.8 mm ID and ≤ 310 mm in length

    or
  - ≥ 2.8 mm ID and ≤ 317 mm in length

[a] The validation studies for all channel/lumen configurations were conducted using a maximum of twenty (20) lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load consisting of two instrument trays and two pouches for a total weight of 19.65 lbs.

The Amsco V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems' **Non Lumen Cycle,** cleared under K083097, K102394 and K111810, can sterilize:[b]

- Non-lumened instruments including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened instruments with stainless steel diffusion-restricted areas such as the hinged portion of forceps or scissors.

[b] The validation studies were conducted using a validation load consisting of two instrument trays and two pouches for a total weight of 19.65 lbs.

The Amsco V-PRO maX Low Temperature Sterilization System's **Flexible Cycle,** cleared under K102330 and K112760, can sterilize single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes in either of two load configurations:

1. Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load.[c]

   The flexible endoscopes may contain either:
   - a single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length
   - or two lumens with:
     - one lumen that is ≥ 1 mm ID and ≤ 998 mm in length
     - and the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length

[c] The validation studies were conducted with two flexible endoscopes, each packaged into a tray with silicone mat and light cord (if not integral to endoscope).

2. One flexible endoscope with a light cord (if not integral to endoscope) and mat and additional non-lumened instruments including instruments with diffusion-restricted areas such as the hinged portion of forceps or scissors.[d]

The flexible endoscope can contain either:

- a single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length
- or two lumens with:
  - one lumen that is ≥ 1 mm ID and ≤ 998 mm in length
  - and the other lumen that is ≥ 1 mm and ≤ 850 mm in length

[d] The validation studies were conducted with a flexible endoscope in a tray with silicone mat and light cord (if not integral to endoscope). Also included in the load were an additional instrument tray and one pouch for a total load weight of 24.0 lbs.

5. Summary of Nonclinical Tests

The Amsco V-PRO 1, V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems have the same or similar intended use and the same technological characteristics as compared to the predicate devices. Performance testing to assess and demonstrate substantial equivalence to the predicates is summarized below.

Test	Result	Conclusion
½ Cycle Modified Total Kill Endpoint Verification	Modified total kill end point analysis was demonstrated. The standard injection weight of 2.1 g and a lower injection weight of 1.457 g resulted in all sterile results for the Lumen Cycle modified stainless steel lumen claims. All survival results were shown at the lowest weight evaluated (0.121 g). Partial positives results were seen at the intermediate injection weights.	PASS
½ Cycle Sterilization Verification of Lumen Claims	The V-PRO Lumen Cycle reproducibly sterilizes the modified stainless steel lumen claims under worst case conditions in a V-PRO Lumen ½ Cycle.	PASS
½ Cycle Sterilization Verification of Double Pouched Lumens	The V-PRO Lumen Cycle reproducibly sterilizes the modified stainless steel lumen claims under worst case conditions in a V-PRO Lumen ½ Cycle in a double pouched configuration.	PASS
Simulated Use Test	Simulated use testing verified the ability of the V-PRO Lumen Cycle to sterilize the modified stainless steel lumen claims under worst case processing conditions.	PASS
In Use Test	The in use investigation demonstrated the ability of the V-PRO Lumen Cycle to sterilize clinically cleaned, patient-soiled medical instruments representative of the modified stainless steel lumen claims.	PASS

Test	Result	Conclusion
Biocompatibility	Residue analysis evaluation has demonstrated biocompatibility after processing in the V-PRO Lumen Cycle.	PASS
Validation of Accessories for use with the V-PRO Lumen Cycle Modified Lumen Claims		
V-PRO Sterilization Trays	The modified stainless lumens claims were successfully sterilized in the V-PRO Sterilization Trays under Lumen ½ cycle worst case conditions.	PASS
Vis-U-All Tyvek Pouches	The modified stainless lumens claims were successfully sterilized in the Vis-U-All Tyvek Pouches under ½ cycle worst case conditions.	PASS

The Amsco V-PRO Low Temperature Sterilization Systems have been tested for conformity and are certified to the following standards:

- EN 61010-1:2001 Safety requirements for electrical equipment for measurement, control and laboratory use. General requirements; Part 1: General Requirements
- EN 60601-1-2:2002 Medical electrical equipment. General requirements for safety. Collateral standard. Electromagnetic compatibility. Requirements and tests.

6. Conclusion

The Amsco V-PRO 1, V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems have been validated to meet the established performance criteria. The results of the Amsco V-PRO Low Temperature Sterilization System verification studies demonstrate that the Lumen Cycle performs as intended and the proposed device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 16, 2013

STERIS Corporation
Mr. Bill Brodbeck
Director, Regulatory Affairs
5960 Heisley Road
MENTOR OH 44060

Re: K131120
Trade/Device Name: Amsco® V-PRO® 1, V-PRO 1 Plus and V-PROmaX Low Temperature Sterilization Systems
Regulation Number: 21 CFR 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: II
Product Code: MLR
Dated: April 19, 2013
Received: April 22, 2013

Dear Mr. Brodbeck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131120

Device Name: **Amsco® V-PRO® 1, V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems**

Indications For Use:

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The parameters for the three V-PRO Cycles are as follows:

Sterilization Cycle	Sterilant injection (g)	# of Injections	Sterilant Exposure Time (min)	Chamber Pressure Prior to Injection (Torr)	Chamber/ Vaporizer Temperature (°C)
Lumen	2.1	4	32	0.4	50/60
Non Lumen	2.1	4	12	1	50/60
Flexible	2.1	4	12	0.4	50/60

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie
2013.07.16 15:06:54 -04'00'

Division Sign-Off)
ivision of Anesthesiology, General Hospital
fection Control, Dental Devices

510(k) Number: K131120